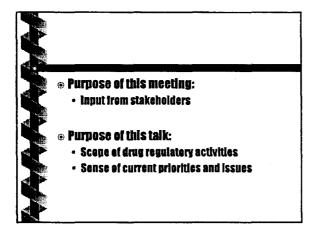
	State of the U.S. Drug Regulatory System
	Janet Woodcock, M.D. August 17, 1998

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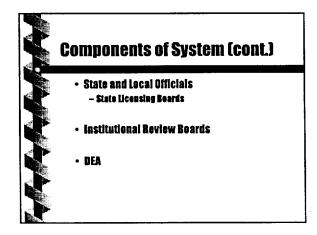
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U.S. Drug Regulatory System o in evolution over much of the 20th Century Mission: Promote and protect public health by assuring that safe and effective drugs are available to Americans. Most recent modification: FDA Modernization Act of 1997

Components of System FDA Center for Drug Evaluation and Research Office of Regulatory Affairs (FDA Field) Office of Chief Counsel Office of the Commissioner



Expectations for the System All marketed drugs are effective and safe in the context of their use. Human drugs are of high quality Generic competition keeps drug prices reasonable All advertising and premetion of drugs is informative and is not faise or misleading Expectations for the System (Cont.) Patients who lack alternatives have access to investigational drugs High quality information on how to use drugs is available including information on children, elderly patients and other groups

Expectations for the System [Cont.] Robust drug development programs, that theroughly protect human subjects, flourish and are productive

Drug Regulatory System: Processes

- Application Review
 - IND, New Drug Application
 - ANDA
- Standard Setting
 - OTC Monographs
 - Standards for Marketing
 - Technical Standards
 - Quality Standards
 - Format and Content

Drug Regulatory System: Processes (cont.)

- Post-marketing safety surveillance (Pharmacovigilance)
 - Pest-marketing trials, registries
 - Spontaneous reporting system

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Drug Regulatory System: Processes

- **© Compliance /Enforcement**
 - Inspections
 - Surveillance
 - Drug sampling
 - Advertising
 - Education
 - Regulatory Actions

Drug Regulatory System: Essential Supporting Activities Research Laboratory Regulatory Science • Pelicy Development Policy Development International Collaboration/Outreach **Essential Supporting Activities** Communication • Drug information/education - Freedom of Information process - Dispute resolution - CDER Ombadsman — Citizen Petitien process Stakehelder feedback - ORA

Essential Supporting Activities: Information Management Information technology Medical Hibrary Electronic submissions Intra- and Internet - use

Essential Supporting Activities: Training Internal Policies Precedures External

FDA Drug Regulatory Program: 1998 Resources*

- 2,561 People
 1,708 CDER
 853 ORA (field)
- \$283,953.80 Budget
 206K CDER
 11.5K Orphan Products
 66 K Field
 *Including User Fee Funding

Application Review: IND Process © Current Performance Level Process well managed and timely First-time-in-human trial issues resolved "Clinical holds" eversight

IND Process: Standards

- International Conference on Narmonization of Technical Requirements for Pharmacouticals (ICH) Standards
 - Good Clinical Practices (ECF)
 - Text celegy pretocets
 - Clinical Testing Guidance
- ⊕ indication specific guidance not updated

Investigational New Drug Process: Issues

- Performance: Extensive performance geals under "PDUFA II"
- 2. Access to investigational Brugs
- 3. Status of institutional Review Boards
- 4. Pediatric Drug Development
- 5. Research: Sherten drug development time & Improve quality (CDDI)

New Drug Review: Performance

- **® Timeliness: Meeting all PDUFA goals**
- Openness: Over 50 Advisory Committee
 Meetings yearly
- Efficiency" Moving toward electronic submission

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New Drug Review: Standards

- Requirements to study children, women, elderly, ethnic groups
- Antibietic resistance
- Over-the-Counter Switches
- Chronically used drugs: patient follow-up

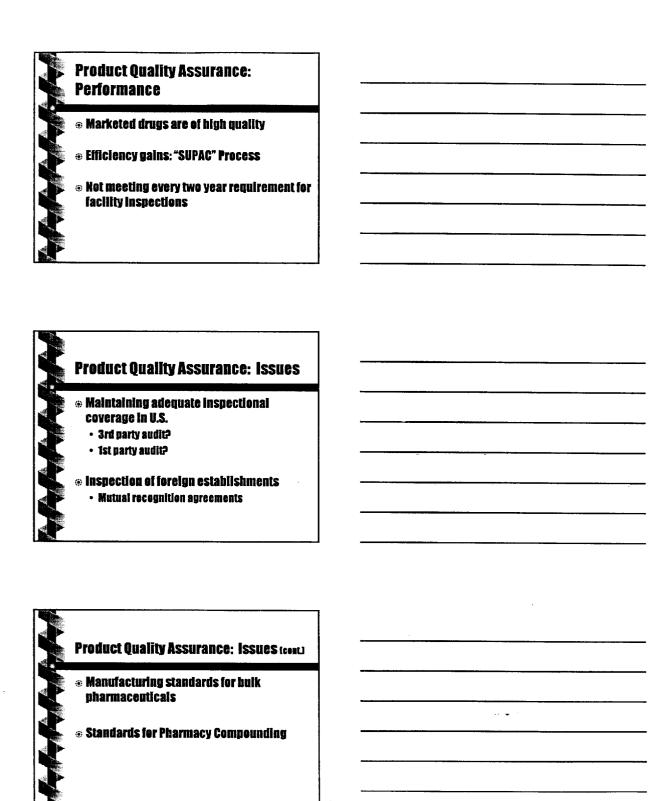


New Drug Review: Issues

Standards

- ⊕ Drug Safety
 - Number of patients studied prior to marketing
 - Benefits to many Vs. risks to few
 - Drug drug interactions
- Radiopharmaceuticals and PET drugs

Application Review: Generic Drugs Current Performance Level - Over 50% ANDA's reviewed in 180 days • Time to marketing has dropped from 40 months (1993) to 19 months (1997) · Additional streamlining occurring Generic Drug Review: Issues Manufacturers calling for further shortening of review times Congressional interest: Barriers to generic competition Research: Non-eral desage forms **Application Review: Supplemental** NDA's (New Uses) FDA "New Use initiative" • Guidance "Providing Clinical Evidence of Effectiveness for Numan Drug and Biological Products" • Guidance "FDA Approval of New Cancer Treatment Uses for Marketed Brug and Biological Products"



Surveillance/Compliance **Health Fraud** Dietary Supplements Marketed unapproved drugs Surveillance: Drug Marketing and **Advertising: Issues** • Birect-te-Consumer Advertising • Disseminating of Reprints: FDAMA • Consumer information on prescription drugs • Pharmaceutical firm's role in managed care Surveillance: Human Subject Protection Audits of clinical trials **& Audits of IRB's** Training IRB's and clinical investigators

international clinical trials

Electronic data capture

Safety of Marketed Drugs Premarket testing will not detect all problems/toxicity's • Rare events · Events caused by use outside approved parameters Medication errors Safety of Marketed Drugs (cont.) **• CBER is upgrading spontaneous reporting** system (passive surveillance) Active surveillance of various kinds has been suggested **Communications** Effective communication linked to drug safety Prescription and OTC labeling Drug development statistics

• Communications research

